



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kostenuik, et al.

Serial No.: 09/843,221

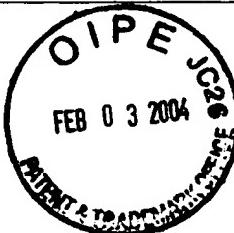
Group Art Unit No.: 1647

Filed: April 26, 2001

Examiner: Christopher J. Nichols, Ph.D.

For: Modulators of Receptors for Parathyroid Hormone
and Parathyroid Hormone-Related Protein

Docket No.: A-665B



INFORMATION DISCLOSURE STATEMENT

BEFORE

**MAILING DATE OF EITHER A FINAL ACTION OR NOTICE
OF ALLOWANCE (37 CFR 1.97(c))**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under the guidelines of 37 CFR 1.97, applicants submit a copy of each of the references listed on the attached supplemental PTO-1449 (Modified) form for consideration by the Examiner.

This Information Disclosure Statement is being filed after three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last, but **before** the mailing date of either:

- (1) a final action under § 1.113 or
- (2) a notice of allowance under § 1.311,
whichever occurs first.

STATEMENT OR FEE

Accompanying this transmittal is:

A a statement as specified in 37 CFR 1.97(e):

STATEMENT

I, the person(s) signing below state:

EXPRESS MAIL CERTIFICATE

*Express Mail® mail labeling number:

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Date of Deposit: February 3, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450..

Printed Name

Signature

- that each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 CFR 1.97(e)(1).

OR

- that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 CFR 1.97(e)(2).

OR

- B. the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$180.00).

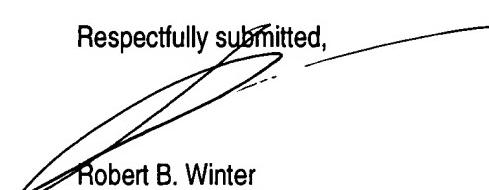
Applicant(s) request(s) consideration of this information and passage of the application to issue.

FEE PAYMENT

Please charge Deposit Account No. 01-0519 in the amount of \$180.00 (37 CFR 1.97(c)). An original and one copy are enclosed.

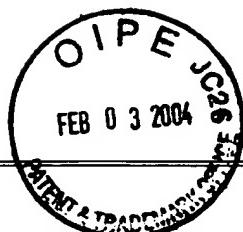
The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 01-0519.

Respectfully submitted,


Robert B. Winter
Attorney/Agent for Applicant(s)
Registration No.: 34,458
Phone: (805) 447-2425
Date: February 3, 2004

Please send all future correspondence to:

US Patent Operations/RBW
Dept. 4300, M/S 27-4-A
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799



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Modified Form PTO-1449

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| Atty. Docket No. | A-665B | Serial No. | 09/843.221 |
| Applicant | Kostenuik, et al. | | |
| Filing Date | April 26, 2001 | Group | 1647 |

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

| EXAMINER'S INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE IF APPROPRIATE |
|---------------------|----|-----------------|-------------|--------------------|-------|-----------|----------------------------|
| | A1 | 5,693,616 | 02 Dec 1997 | Krstenansky et al. | | | |
| | A2 | 5,807,823 | 15 Sep 1998 | Krstenansky et al. | | | |
| | A3 | 5,874,086 | 23 Feb 1999 | Krstenansky et al. | | | |
| | A4 | 6,417,333 B1 | 09 Jul 2002 | Bringhurst et al. | | | |
| | A5 | | | | | | |
| | A6 | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION YES NO |
|--|----|-----------------|------|---------|-------|-----------|-----------------------|
| | B1 | | | | | | |
| | B2 | | | | | | |

OTHER DOCUMENTS (Including Publisher, Author, Title, Date, Pertinent Pages, Etc.)

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| | C1 | Baumann et al., Response of Cortical Bone to Antiresorptive Agents and Parathyroid Hormone in Aged Ovariectomized Rats. BONE, 16(6): 247-253. (Feb 1995). |
| | C2 | Berning et al., Tibolone and its effects on bone: a review. CLIMACTERIC, 4(2):120-136. (June 2001). |
| | C3 | Crandall, C., Parathyroid Hormone for Treatment of Osteoporosis. ARCHIVES OF INTERNAL MEDICINE, 162: 2297-2309. (11 Nov 2002). |
| | C4 | Hodsman, A. B. et al., Biochemical responses to sequential human parathyroid hormone (1-38) and calcitonin in osteoporotic patients. BONE AND MINERAL., 9(2): 137-152. (May 1990) |
| | C5 | Hofbauer, L. C. et al., Stimulation of Osteoprotegerin Ligand and Inhibition of Osteoprotegerin Production by Glucocorticoids in Human Osteoblastic Lineage Cells: Potential Paracrine Mechanisms of Glucocorticoid-Induced Osteoporosis. ENDOCRINOLOGY, 140(10): 4382-4389. (Oct 1999) |
| | C6 | Kostenuik, P. J. et al., OPG and PTH(1-34) Have Additive Effects on Bone Density and Mechanical Strength in Osteopenic Ovariectomized Rats. ENDOCRINOLOGY, 142(10): 4295-4304. (Oct 2001) |
| | C7 | Li, M. et al., Parathyroid Hormone Monotherapy and cotherapy with Antiresorptive Agents Restore Vertebral Bone Mass and Strength in Aged Ovariectomized Rates. BONE, 16(6): 629-635. (Jun 1995) |
| | C8 | Morley, P. et al., Parathyroid Hormone: An Anabolic Treatment for Osteoporosis. CURRENT PHARMACEUTICAL DESIGN, 7(8): 671-687. (May 2001). |
| | C9 | Reeve, J. et al., Treatment with parathyroid peptides and estrogen replacement for severe postmenopausal vertebral osteoporosis: prediction of long-term responses in spine and femur. J. BONE MINR. METAB., 19(2): 102-114. (09 March 2001). |

EXAMINER:

Date Considered:

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Sheet 2 Of 2

Modified Form PTO-1449

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

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|------------------|-------------------|---------------|
| Atty. Docket No. | A-665B | Serial No. |
| Applicant | Kostenuik, et al. | |
| Filing Date | April 26, 2001 | Group 1647 |

EXAMINER'S INITIALS

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| C10 | Rosen et al., CLINICAL REVIEW 123: HOT TOPIC Anabolic Therapy for Osteoporosis. THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM, 86(3): 957-964, (Mar 2001). |
| C11 | Tanizawa et al., Effects of human PTH (1-34) and bisphosphonate on the osteopenic rat model. TOXICOLOGY LETTERS. 102-103: 399-403, (Dec 1998). |
| C12 | Wronski, T. J., et al., Parathyroid Hormone is More Effective Than Estrogen or Bisphosphonates for Restoration of Lost Bone Mass in Ovariectomized Rats. ENDOCRINOLOGY, 132(2): 823-831, (Feb 1993) |
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